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ATTACHMENT 1

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**510(K) SUMMARY  
MYELOTec MYELOSCOPE SYSTEM**

**Submitter Information:**

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**Name of the Device:**

Trade or Proprietary Name: Myelotec Myeloscope

Common Name: Flexible fiberoptic scope with guiding catheter

Classification Name: Arthroscope and Accessories (21 CFR Part 888.1100)

**Identification of Legally Marketed Devices To Which The Submitter Claims  
Equivalence:**

The Myelotec, Inc. Myeloscope is similar in design and/or intended use to several legally marketed flexible fiberscope endoscopes. These include the Danek Spinal Epidural Endoscope Systems (K930191) and the Ultra-Vu Endoscope Systems (K913129). These are flexible fiberoptic systems used for "micro-endoscopic" applications in small body cavities and spaces.

**Description of the Subject Device:**

The Myelotec Myeloscope is a flexible fiberoptic system that includes a video guided catheter that allows steering of the fiberoptic scope. The fiberoptic scope is a reusable device that is supplied non-sterile with instructions for cleaning, sterilization and re-use. The video guided catheter is a sterile, disposable device.

The optical performance characteristics of the Myelotec Myeloscope are similar to the predicate devices.

Performance testing of the video guided catheter shows that the catheter is capable of flexing the Myeloscope optics 30 degrees to the right and left for 250 cycle without damage to the tip bonds or steering mechanism.

Safety testing included biocompatibility for patient contacting materials.

#### **Intended Use of the Subject Device**

The Myeloscope is intended to be used by physicians for the illumination and visualization of tissues of the epidural space in the lumbar and sacral spine for the purpose of assisting in the diagnosis of disease.

#### **Technological Characteristics of the Subject Device:**

There are no significant technological characteristics between the Myelotec Myeloscope and the predicate devices. Optical and mechanical performance and materials are similar.

Non-clinical testing on the Myelotec Myeloscope included optical, mechanical, sterilization assurance and re-use validations.